ISRCTN13320231 https://doi.org/10.1186/ISRCTN13320231

Comparison of two analgesic combinations for reno-ureteral colic treatment

Submission date
04/03/2022

Recruitment status
No longer recruiting

Registration date
04/04/2022

Overall study status
Completed

Last Edited
30/08/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Reno-ureteral colic happens when a stone gets lodged in your urinary tract, often in a ureter. The stone stretches and widens the area, causing intense pain.
The standard treatment consists of a painkiller (diclofenac) given directly via a vein, which is commonly combined with butylhyoscine. Such a combination lacks clinical evaluation in the literature, and a clinical practice guidelines suggest ketorolac and metamizole as second-line treatments. Given the complex behavior of reno-ureteral colic, the ketorolac and metamizole combination may represent a better clinical practice to benefit patients. The present study is aimed to evaluate the efficacy of ketorolac/metamizole versus diclofenac/butylhyoscine for reno-ureteral colic management.

Who can participate?
Patients with reno-ureteral colic and aged at least 18 years

What does the study involve?
Patients will be randomly allocated to a single dose of either ketorolac/metamizole or diclofenac /butylhyoscine, and will be monitored from baseline to 45 min.

What are the possible benefits and risks of participating?
The benefits include evidence-based management for reno-ureteral colic treatment, and the risks for such safe drugs might involve hypersensitivity to formulations.

Where is the study run from?
Instituto Mexicano del Seguro Social (Mexico)

When is the study starting and how long is it expected to run for?
September 2021 to September 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Julieta Godoy-Caballero, godoyjulieta957@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R-2021-3201-168

Study information

Scientific Title
Analgesic efficacy of ketorolac/metamizole versus diclofenac/butylhyoscine for reno- ureteral colic management in a primary-care hospital emergency service

Acronym
KMDB

Study objectives
Ketorolac/metamizole analgesic efficacy is similiar to diclofenac/butylhyoscine in reno-ureteral colic management

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2021, IMSS Local Health Research Committee 3201 (Comite Local de investigacion en salud del IMSS 3201, 41 street, Mérida Yucatán, México; no telephone number provided; comite.eticainv@imss.gob.mx), ref: R-2021-3201-168

Study design
Single center interventional blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reno-ureteral colic management

Interventions
Participants will be randomized 1:1 to receive the intervention or the comparison treatment. This process will occur when the patient arrives at the Emergency service from the primary-care hospital and will be performed with sealed envelopes containing the written informed consent, the pain-scale questionnaires, and a colored mark indicating the treatment that should be given.

Patients in the intervention group will receive a single intramuscular dose of ketorolac (30mg) /metamizole (1g).
Patients in the comparison group will receive diclofenac (75mg)/ butylhyoscina (20mg).
Patients are then monitored for 45 minutes.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ketorolac, metamizole, diclofenac, butylhyoscine

Primary outcome(s)
Pain is measured using a visual analogue scale (VAS) at baseline, 10, 20, and 45 min

Key secondary outcome(s))
The brief pain inventory (short form in Spanish) will be applied to assess the severity of pain and its impact on functioning at baseline

Completion date
20/09/2022

Eligibility

Key inclusion criteria

1. Aged 20 to 60 years
2. Clinical signs and symptoms of reno-ureteral colic

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Hypersensitivity to any of the tested drug formulations
2. Patients with severe reno- ureteral colic (with fever and chronic pain)
3. Grade III and IV renal insufficiency
4. Patients will be excluded if they have any pre-existing treatment that might interact with the tested drug
5. Patients will be excluded if they possess pre-existing digestive tube bleeding

Date of first enrolment
01/01/2022

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
Mexico

Study participating centre
Instituto Mexicano del Seguro Social
42 street, Serapio rendon
Mérida
Mexico
97285

Sponsor information

Organisation
Mexican Social Security Institute

ROR
https://ror.org/03xddgg98

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The database will be available upon reasonable request.
godoyjulieta957@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			10/03/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		01/11/2021	10/03/2022	No	No